K062758

510(k) Summary

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Submitter:

DIROS TECHNOLOGY INC
232 Hood Road
Markham, ON
L3R3K8, Canada

SEP 27 2006

Contact:

Mr. George Darmos
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Date: July 27, 2006

Trade Name: OWL URF-3AP

Common Name: OWL Radiofrequency System

Classification Name: Generator, Lesion, Radiofrequency

Regulatory Class: II

Product Code: GXD

Regulation Number: 882.4400

REGISTRATION NO: 8043398

OWNER/OPERATOR NO: 9001301

Predicate Devices:

We are making the claim that the DIROS OWL URF-3AP is substantially equivalent to the predicated devices listed in the chart below.

LEGALLY MARKETED PREDICATE DEVICE	MANUFACTURE NAME	REGULATORY CLASS AND PRODUCT CODE	510(K) REGISTRATION NUMBER
OWL URF-2AP	DIROS TECHNOLOGY INC	Class II/GXD	K021869
PMG-115	BAYLIS MEDICAL COMPANY	Class II/GXD	K020354

The rationale of declaring the DIROS OWL URF-3AP is substantially equivalent to the above 2 predicate devices is based on the following:

- ✓ Same Indications for use: All systems provide treatments by making heat ablative lesions in central or peripheral nerve tissue for the treatment of movement disorders or for the relief of pain. All systems are using the same fundamental scientific technology.
- ✓ Similar key design technical characteristics- Pain relief is achieved by the controlled heating of the area surrounding the electrode tip. A thermosensor in the probe is used to control tissue temperature. Impedance values are displayed to guard against unsafe conditions.
- ✓ Same/similar components for treatment and measurement.
- ✓ Similar size, power source, and performance

Description:

The OWL radiofrequency generator URF-3AP is used by qualified medical personnel to make heat ablative lesions in central or peripheral nerve tissue for the treatment of movement disorders or for the relief of pain. The lesions are ablative in order to be therapeutic; i.e. the destruction of a small portion of the thalamus within the brain interferes with the motor pathway causing the tremor of Parkinson's disease, thereby relieving the tremor; or the

destruction of the facet joint nerves in the lumbar vertebrae to block pain transmission by these nerves and thereby relieve certain types of low back pain.

The URF-3AP supplies up to 50 Watts of Radio Frequency energy at 481kHz in bipolar or monopolar modes under power or temperature control while continuously monitoring and displaying actual power delivered, measured probe temperature, time of power duration, and measured impedance.

When used with monopolar probes, the system also delivers low-frequency stimulus pulses in either voltage or current controlled modes.

Indications for Use:

The DIROS® URF-3AP LESION GENERATOR is intended for the following:

1. Lesioning nerve tissue for functional neurosurgical procedures such as thalamotomies, pallidotomies, tractomies, and myelotomies; or
2. radiofrequency heat lesion procedures for the relief of pain

Summary of Performance Testing:

A risk analysis identifying potential hazards and documenting mitigations of the hazards has been developed and applied as part of the DIROS OWL URF-3AP product development cycle. The risk analysis is based on EN 1441/ISO14971 - Risk Analysis for Medical Devices.

Testing was performed to validate the functional performance of the DIROS system. In particular, specific performance testing of the software was performed to show that the performance was met.

The DIROS OWL URF-3AP has been subjected to performance testing to applicable safety, electrical, mechanical, EMC standards. The DIROS OWL URF-3AP system has been evaluated and has passed all mechanical and electrical safety according to CSA International. Standards that were investigated are: IEC 60601-1, UL 60601-1 and CAN/CSA C22.2No.601.1-M90 certified. The URF-3AP has also been evaluated and satisfies the requirements to IEC 601-2-2 Medical electrical equipment, Part 2: Particular requirements for the safety of high frequency surgical equipment.

Conclusion:

As stated above, DIROS TECHNOLOGY INC.'s conclusion is that the DIROS OWL URF-3AP is safe and effective and complies with the appropriate medical standards and is substantially equivalent to the above identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Diros Technology, Inc.,
% Mr. George Darmos
President
232 Hood Road
Markham, Ontario
Canada L3R 3K8

SEP 27 2006

Re: K062758
Trade/Device Name: OWL Radiofrequency System, Model URF-3AP
Regulation Number: 21 CFR 882.4400
Regulation Name: Radiofrequency lesion generator
Regulatory Class: II
Product Code: GXD, GXI
Dated: August 3, 2006
Received: September 15, 2006

Dear Mr. Darmos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062758

Device Name: OWL Radiofrequency System, Model URF-3AP

Indications For Use:

The OWL Radiofrequency System, Model URF-3AP, intended use is for:

1. Lesioning nerve tissue for functional neurosurgical procedures such as thalamotomies, pallidotomies, tractomies, and myelotomies; or
2. radiofrequency heat lesion procedures for the relief of pain

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062758